DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 4, 2014

Telesystems Co., Ltd.
% Mr. Claude Berthoin
President
Denterprise International, Inc.
110 East Granada Blvd.
ORMOND BEACH FL 32176

Re: K133797
Trade/Device Name: Qmaster-H/Revo
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: August 1, 2014
Received: August 4, 2014

Dear Mr. Berthoin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133797

Device Name
QRmaster-H/Revo

Indications for Use *(Describe)*

QRmaster-H/Revo is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The device accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume, and displaying both 2D images and 3D renderings. This technique is known as cone beam computed tomography, or CBCT.

All devices are sold by or on the order of a physician. They are not for use by the general public or over-the-counter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Date Prepared: December 10, 2013

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Trade Name: QRmaster-H/Revo
Common Name: Cone Beam Computed Tomography (CBCT) X-Ray System
Classification Name: Dental Computed Tomography X-Ray System (21 CFR 892.1750, Product Code OAS)

Predicate Devices: Hyperion (K113497); Cefla Dental/MyRay, Italy
Orthophos XG (K103711); Sirona Dental, Germany
NewTom VG (K072357); Cefla Dental/QR, Italy

Device Description: QRmaster-H/Revo is an extraoral 2D (panoramic) and 3D (CBCT) x-ray imaging system for use by dental professionals. The device is designed to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. To accomplish this it uses a cone-shaped x-ray beam projected on a flat panel detector to capture a rapid series of 2D images using the standard narrow beam technique. Such images from a single 360^{o} scan are reconstructed with special software to be viewed on 3D viewing stations (PCs) that are not part of the system.

The system makes use of a single flat panel detector for both panoramic and cone beam images. Three field of views (FOVs) provide targeted regions of interest that can be positioned by panoramic scout, two-dimensional scout, or four positioning laser beams.

QRmaster-H/Revo includes firmware to operate the device through a control panel attached to the main device. The device also includes image acquisition software that stores 3D images in standard DICOM format for export to third party viewing or image management software not part of the system. Users are expected to have or acquire such image management software for communication both with the device's image acquisition software and with third party 3D-viewing software. These latter applications are readily available in the domestic marketplace.

Indications For Use: QRmaster-H/Revo is a dedicated X-ray imaging device that acquires a 360-degree rotational X-ray sequence of images for use as diagnostic support in radiology of the dento-maxillo-facial complex and in the field of maxillofacial surgery. The device accomplishes this task by reconstructing a three-dimensional matrix of the examined volume, producing two-dimensional views of this volume, and displaying both 2D images and 3D renderings. This technique is known as cone beam computed tomography, or CBCT.

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Comparison to Predicates – QRmaster-H/Revo is intended for 2D panoramic diagnostic examination of dentition, jaws, and oral structures, the same as all three predicates. The device is also intended for 3D tomographic examination of dento-maxillo-facial areas and to support maxillofacial surgery, the same as two predicate devices with CBCT technology (Orthophos XG and NewTom VG).

Table 5 on the next page compares technological features between the subject and predicate devices. It shows the QRmaster-H/Revo and predicates share the same fundamental scientific technology. All are dedicated high-end x-ray imaging systems for dentistry.

More specifically, QRmaster-H/Revo is a PAN/CBCT x-ray system. All three predicates share the subject's 2D PAN technology, whereas two of the three share its 3D CBCT technology (Orthophos XG and NewTom VG). Two predicates also include CEPH technology for orthodontists (Hyperion and Orthophos XG), a feature not included in the subject device.

All devices feature similar x-ray generation technology, while QRmaster-H/Revo shares the same single-panel x-ray detector technology as NewTom VG.

Scan performance is continuous for both QRmaster-H/Revo and Hyperion. Exposure times are higher for the subject device, but measured effective exposure is equal to or lower than the predicates (as discussed in Section 12, Substantial Equivalence Discussion).

None of the differences in technological features between the subject and predicate devices raise new issues of safety or effectiveness.

Table 5 - Comparison of Technological Features

Devices	QRmaster-H/Revo (Subject)	Hyperion	Orthophos XG	NewTom VG
510(k) Number	NA	K113497	K103711	K072357
Manufacturer	Telesystems (Japan)	Cefla Dental/MyRay (Italy)	Sirona Dental (Germany)	Cefla Dental/QR (Italy)
Device Photo				
Common Name	PAN & CBCT X-Ray System	PAN & CEPH X-Ray System	PAN, CEPH & CBCT X-Ray System	PAN & CBCT X-Ray System
X-Ray Generator				
X-Ray Source	High Frequency, Rotating Anode	High Frequency, Rotating Anode	High Frequency, Rotating Anode	High Frequency, Rotating Anode
Shape of X-Ray Beam	Fan-shaped x-ray beam and cone beam for tomography x-ray	Fan-shaped x-ray beam	Fan-shaped x-ray beam and cone beam for tomography x-ray	Cone beam for tomography x-ray
X-Ray Detector				
Single Image Detector?	YES	NO	NO	YES
Image Detector (PAN)	Amorphous silicon flat panel detector (Hamamatsu)	Digital CCD linear detector, repluggable for CEPH exposure	Digital CCD linear detector, repluggable for PAN exposure	Amorphous silicon flat panel detector (Varian)
Image Detector (CBCT)	Amorphous silicon flat panel detector (Hamamatsu)	NA	Digital FPD with CMOS technology, integrated for 3D exposure technique	Amorphous silicon flat panel detector (Varian)
Scintillator (CBCT)	CsI	NA	Not documented	CsI
Scan Performance				
Type of X-Ray Emission	Continuous for PAN and CBCT exams	Continuous for PAN and CEPH exams	Not documented	Pulsed for CBCT exams
Exposure Time (Standard Pan)	12 s, continued exposure	9.3 s, continued exposure	14.1 s	NA
Exposure Time (CBCT)	18 s, effective radiation time	NA	3.2-5.0 s, effective radiation time	3.6 s – 5.4 s, effective radiation time
FOV (CBCT - Voxel Size - O X H cm)	5.0 X 4.5 cm 9.5 X 4.5 cm 9.5 X 9.0 cm	7 cm (H.R. Zoom 4") 11 cm (6" detector) 15 cm (9" detector)	8.0 X 8.0 cm	8.0 X 10.0 cm

Performance Data: Clinical images were examined by a qualified professor at Asahi University School of Dentistry and found to be diagnostically relevant and reliable. Sample 2D and 3D images utilizing test phantoms are also included in the submission.

Biocompatibility Assessment: Biocompatibility testing is not warranted since surfaces in contact with users are covered with single-use protective barriers during use.

Software and Risk Analysis: A software level of concern analysis that included a device risk analysis in conformance with ISO 14971 was performed. Results of that analysis determined the residual risks inherent in the use of QRmaster-H/Revo are "acceptable." Verification and validation of the software included tests that confirmed its functionality.

EMC and Electrical Safety Testing: Independent laboratory and in-house testing was performed to demonstrate conformance with recognized electrical (60601 et al) and laser device (60825-1) standards.

FDA Guidance Compliance: The subject device and this petition comply with the following FDA guidance documents: (a) *Pediatric Information for X-Ray Imaging Device Premarket Notifications*, draft guidance issued on May 10, 2012; (b) *Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices*, issue on August 6, 1999; (c) *Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22*, issued on June 24, 2007; and (d) *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005.

Conclusions: Both intended use and fundamental scientific technology are the same in the subject and predicate devices, and any differences in technological features do not raise new issues of safety or effectiveness. A comparison of such features, combined with performance data that includes clinical evaluation of device images, a software and device risk analysis, and electromagnetic compatibility as well as electrical and laser safety tests support the conclusions that QRmaster-H/Revo is safe for its intended use and is substantially equivalent to the predicate devices.